N THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
(HOUSTON DIVISION)

GAYATHRI MURTHY,	§	
Plaintiff,	§	
	§	
v.	§	CASE NO. _____
	§	
ABBOTT LABORATORIES,	§	
Defendant.	§	JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Gayathri Murthy files this suit against Abbott Laboratories, Inc., and for cause of action would show the Court the following:

Nature of the Case

1. This is a diversity jurisdiction, personal injury products liability case. Plaintiff Gayathri Murthy participated in an Abbott clinical trial and was infused with Abbott's blockbuster arthritis drug "Humira" from approximately February 2005 through January 2006. Ms. Murthy was subsequently diagnosed with Stage III, large B-cell lymphoma for which she underwent chemotherapy treatment. The Plaintiff alleges, *inter alia*, that Abbott and its agents, including the physicians and other healthcare professionals who ran the trial, failed to provide a legally proper warning regarding the risks of Humira, including the risk of cancer, and that her infusion with this drug caused her cancer.

Parties

2. Plaintiff Gayathri Murthy is a resident of Houston, Harris County, Texas. She has worked as an EKG instructor at St. Luke's Hospital in Houston for nearly 30 years.

3. Defendant Abbott Laboratories is a corporation organized and existing under the laws of Illinois, having its principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Presumably its counsel will accept a Rule 4 Notice and Acknowledgment so that no formal service of process will be necessary. If service of process is necessary, Abbott's agent for same is Laura J. Schumacher, 100 Abbott Park Road, Abbott Park, Illinois, 60065. Abbott conducts business throughout the United States, including in the State of Texas.

Jurisdiction and Venue

4. This Court has diversity jurisdiction under 28 U.S.C. § 1332. The amount in controversy, exclusive of interest and costs, is substantially in excess of Seventy Five Thousand Dollars ($75,000). Venue is proper in this District by virtue of 28 U.S.C. § 1391 and the stipulation between the parties regarding the dismissal of Ms. Murthy's prior lawsuit against Abbott.

Prior Lawsuit/Timeliness of Case

5. Ms. Murthy previously filed suit against Abbott, and one of its subsidiary companies, in the United States District Court for the District of Massachusetts under

C.A. No. 2008-00328. That case was dismissed without prejudice pursuant to a stipulation between the parties. One of the conditions of the stipulation was that any refiling would have to be accomplished by January 12, 2011, in federal court in either Texas or Illinois. This refiling is being accomplished within that time period. Accordingly, the suit is timely.[1]

Facts

This suit has been necessitated by virtue of the following facts.

The TNF Blocker "Miracle"

6. "Tumor Necrosis Factor" [hereinafter "TNF"] is a naturally occurring substance in the human body. TNF is critical to the workings of the body's immune system. It is believed to act as a natural killer of cancer causing tumor cells in the body.

7. Humira, the generic name of which is "ADALIMUMAB," is a "biologic" drug, which means that it is a medicine that has been constituted or reconstituted from natural substances in the body. It was the first such drug in its class that was derived from actual human cells. More specifically, Humira (adalimumab) is alleged to be a recombinant human IcG1 antibody that neutralizes and/or blocks the activity of the

[1] In the prior lawsuit Ms. Murthy alleged that Abbott's fraudulent concealment tolled and precluded any claim of limitations. If, for any reason, Abbott alleges a statute of limitations defense, that allegation in response is hereby alleged.

pro-inflammatory cytokine known as tumor necrosis factor ("TNF"). A cytokine is a non-antibody protein that can be made by a wide range of cell types.

8. The first authorized use or "indication" for the TNF blockers in this country was to treat rheumatoid arthritis [hereinafter "RA"]. In the treatment of rheumatoid arthritis, Humira is believed to bind specifically to TNF and block its interaction with certain cell surface TNF receptors, thereby interfering with endogenous TNF activity.

9. The TNF blocker class of drugs have been heralded by some as a "miracle" treatment for rheumatoid arthritis.[2] Undoubtedly, they do help many people. However, in the treatment of any disease with powerful medications, it is always very important for both the prescribing physician and the patient to be able to balance the potential benefits of a medication against the known risks. In the case of Humira, Abbott and its agents, including its clinical investigators like Dr. Jovan M. Popovich, who prescribed the Humira to Ms. Murthy, have downplayed the risk of side effects, including the very real and very dangerous risk of developing lymphoma or other forms of cancer.

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[2] Zashin, ARTHRITIS WITHOUT PAIN, *The Miracle of the TNF Blockers*, (Sarah Allison Publishing Company, 2004). The foreword reflects that the principal author, "Dr. Scott J. Zashin has been a paid consultant and/or speaker for the companies whose products are listed in this book." On information and belief it is alleged that Abbott is one of the companies that paid Dr. Zashin, and further that Abbott provided financial or other support for the publication of the book.

10. From a financial perspective, Humira has certainly been a "miracle" or "blockbuster" for Abbott. Humira first received approval from the U.S. Food and Drug Administration [FDA] on December 31, 2002 for the treatment of moderately to severely active rheumatoid arthritis. Humira was launched in the United States at the beginning of 2003 and reached sales of approximately $246 million in its first year alone. By 2005, the year that Humira was prescribed to Gayathri Murthy, sales had reached $1.4 billion. Since that time, sales revenues have continued to grow. The 2009 sales were approximately $5.5 billion, and the sales projections of Humira for 2010 are approximately $6.8 billion.

"HERO"

11. Ms. Murthy was first diagnosed with rheumatoid arthritis in late 2004. Her primary care physician referred her to Houston rheumatologist Dr. Jovan M. Popovich. He began her treatment with Methotrexate, a long-standing medication for RA. However, unbeknownst to Ms. Murthy, Dr. Popovich was not an independent "learned intermediary" who could make medication decisions without regard to the financial consequences to him. Rather, he was a paid clinical investigator for Abbott.

12. Specifically, Dr. Popovich was the "Principal Investigator" for a clinical study entitled "*Humira Efficacy Response Optimization Study in Subjects With Active Rheumatoid Arthritis*," which was given the attractive acronym of "HERO." This study was initiated and paid for by Abbott. The medication was provided to study

participants free of charge, and the physicians, like Dr. Popovich were paid by Abbott to use it to treat patients in the study, including Ms. Murthy. Consequently, with regard to the subject of warnings, and "informed consent," Dr. Popovich was functioning as Abbott's agent, not the patient's.

13. Exhibit A hereto is a document prepared by Abbott entitled "*Consent to Participate in a Clinical Research Study*". It is incorporated by reference herein. Effectively, this is Ms. Murthy's "Informed Consent" agreement for this study. It is dated January 17, 2005, signed by both Ms. Murthy and Dr. Popovich, and is a binding contract between Abbott and Ms. Murthy. The "Risks of Adalimumab (HUMIRA®)" are discussed on page 5 of 12. With regard to lymphoma or other cancers, it states only the following:

> Occasionally (about 2%), various types of cancer including lymphoma (cancer of lymph node) are observed in subjects taking adalimumab. The relationship of adalimumab with these cancers is currently unknown.

14. Dr. Popovich did test Ms. Murthy for tuberculosis and, as far as she was made aware, that was the most serious potential side effect of Humira. However, prior to agreeing to participate in the HERO Study, Ms. Murthy asked Abbott's agent, Dr. Popovich about the risk of <u>other</u> side effects from the medication. His response was simply, "have you seen the side effects of aspirin?"

15. In addition to the lengthy Informed Consent form, which was presented to Ms. Murthy in a perfunctory manner, she was shown a videotape, produced and

provided by Abbott to Dr. Popovich for the express purpose of showing to potential patients prior to their agreement to participate in the HERO study. The video, which lacks the "fair balance" that FDA regulations require, paints a rosy picture of therapy with Humira, and does little if anything to alert the patient to the very real risk of life-threatening Humira-induced cancer.

16. The information about side effects on the Informed Consent form was incomplete and misleading, even by the inadequate standards of that time. For example, the full package insert in the July 2004 label under Warnings stated not only that in the controlled portions of the clinical trials of all TNF-blockers, "more lymphoma cases were observed in patients receiving the TNF-blockers," but also "Specifically, [that] 2 lymphomas were observed among 1380 Humira-treated patients with moderate to severe rheumatoid arthritis verses 0 among 690 control patients." Obviously, the "relative risk" or "odds ratio" from this data is one of *infinity*. It is alleged on information and belief that this increase in risk, as contained in the July 2004 labeling, was statistically significant.

17. The July '04 labeling further informed that "in the controlled and open-label portions of the clinical trials, 10 lymphomas were observed in 2,468 patients" and warned that "**This is approximately 5-fold higher than expected in the general population.**"

18. Moreover, nothing in the form presented by Abbott's agent Dr. Popovich to Ms. Murthy, or in the verbal presentation, alerted Ms. Murthy to the fact that in March 2003 the FDA's Arthritis Advisory Committee had "concluded that a connection between TNF blockers and lymphoma was *possible*, but could not be established with *certainty." See* Zashin, *supra* and source cited on p. 87, n.25. Again, it is alleged on information and belief that Abbott has paid Dr. Zashin to write or speak on behalf of Humira, and that it provided financial or other assistance (to include technical writing assistance) for the publication of this book.

19. Both Abbott and its agent, Dr. Popovich, had an obligation to convey complete and truthful information to Ms. Murthy about the side effects of Humira, including the very significant risk that this medication could trigger iatragenic cancers. Needless to say, if Ms. Murthy had been fully informed, *i.e.,* "warned," about the dangers of Humira-induced lymphoma, she would not have agreed to participate in Abbott's HERO study or otherwise to infuse or inject Humira into her body.

Belated Warnings Directly to Patients

20. Abbott did nothing to warn patients directly about the risks of Humira-induced cancers until the FDA required them to do so in 2009. However, in the FDA-mandated Patient Medication Guide dated September 2010 Abbott states :

> "For children and adults taking TNF-blocker medicines, including HUMIRA, the chances of getting lymphoma or other cancers may increase."

> "Patients with RA, especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma."

21. Moreover, on the home page of the website that Abbott uses to promote Humira directly to patients and the public, www.humira.com, it states "**Certain types of Cancer**. There have been cases of unusual cancers in children and teenagers using TNF-blocker medicines. For children and adults taking TNF-blocker medicines, including HUMIRA, *the chance of getting lymphoma or other cancers may increase."* [Bold in original; italics added].

22. Even today, however, Abbott does nothing to *quantify* that risk for patients so that they can make fully informed decisions regarding their own bodies. But they do provide more specific data to physicians. For example, under IMPORTANT SAFETY INFORMATION on the Humira Pro website, for Health Care Professionals, Abbott states:

> "In the controlled and open-label portions of Humira clinical trials, there was an approximately **3-fold higher rate** of lymphoma than expected in the general population."

23. Abbott had the data in its possession by January 2005 to alert people to the 3- to 5-fold potential risk of cancer for patients taking Humira. Gayathri Murthy was entitled to full and fair disclosure of this information before she began to infuse Humira.

Cancer

24. Ms. Murthy received "free" Humira from Abbott for approximately two months during her participation in the HERO study. Following her completion of the study, Plaintiff continued to receive Humira injections until approximately January 2006.

25. In February 2006, Mrs. Murthy felt swelling and pain in the right side of her neck and went to her doctor. She was subsequently diagnosed with Stage III large B-cell lymphoma for which she underwent chemotherapy treatment. The rheumatologist who made the diagnosis (not Dr. Popovich) instructed Ms. Murthy to immediately cease taking Humira. The direct and actual cause of the Plaintiff's lymphoma was her infusion of Humira.

26. In addition to suffering personal physical injury, as a result of her diagnosis of lymphoma Plaintiff also suffered lost wages and other economic injury for which the Defendants are liable.

27. Fortunately, Ms. Murthy's lymphoma is now in remission. However, she still must be monitored via radiation studies, and, as a result, her lifetime risk of cancer has been increased.

Causes of Action

The foregoing facts give rise to legally cognizable claims against Abbott under the common and/or statutory law of Texas and/or Illinois, as follows:

28. FIRST – BREACH OF CONTRACT. Page 7 of 12 of Ms. Murthy's agreement with Abbot, under the heading "**COMPENSATION FOR INJURY**," provides the following:

> If, during your participation in this study and in the judgment of the study doctor and Abbott Laboratories, any injury occurs to you as a direct result of this study, Abbott Laboratories agrees to pay all reasonable medical expenses incurred by you necessary to treat the injury provided you have followed the directions of the study doctor. . . .You still have the right to make a claim through the legal system even if you sign this form, accept medical care, or accept payment for medical expenses.

There is an implied covenant of good faith and fair dealing with regard to the "judgment" and "directions" of the "study doctor." Although Dr. Popovich himself declined to treat Ms. Murthy once her participation in the HERO study had terminated, and he was relegated to normal insurance reimbursement for compensation, because Ms. Murthy's cancer was a "direct result" of this study, Abbott is contractually bound to pay "all reasonable medical expenses *incurred*" to treat the cancer and to monitor Ms. Murthy for recurrence of same throughout her lifetime. Under the breach of contract theory, all attorneys fees incurred for pursuing this theory of liability are also recoverable.

29. SECOND - STRICT LIABILITY. Plaintiff asserts a cause of action for strict products liability under the statutory and common law Texas and/or Illinois. Products theories include design defect, failure to warn, and misrepresentation.

30. THIRD - NEGLIGENCE. Defendant Abbott directly or indirectly, negligently and/or defectively made, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold Humira throughout the United States. Consequently, Abbott had a duty to exercise reasonable care in the researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling of the drug.

31. Defendant and its agent Dr. Popovich breached that duty and were negligent in their actions and omissions toward Plaintiff in ways which include, but are not limited to, the following:

a. Failure to include adequate warnings with the drug that would alert Plaintiff's prescribing physician and Plaintiff to the potential risks and serious side affects of the drug, including lymphoma;

b. Failure to adequately and properly test the drug both before and after placing the drug on the market;

c. Failure to adequately warn Plaintiff that all patients, including Plaintiff, should be pre-screened for malignancies or pre-malignancies prior to therapy with Humira, or to insist that, as a part of the HERO study, such screening be implemented; and

d. Failure to display the warnings that were provided in a manner which would properly alert Plaintiffs' prescribing doctor and, more importantly in this *sui generis* case, the Plaintiff herself as to the seriousness of the risk of developing lymphoma that had been reported in association with the drug.

32. But for Defendant's negligent conduct as described herein, Plaintiff would not have ingested the drug and would not have suffered the personal injuries and economic harm alleged herein. As a direct and legal result of the negligence of Defendant and/or its agent(s), Plaintiff has sustained serious and permanent injuries including, but not limited to lymphoma, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and losses are continuing in nature as she will have to be routinely evaluated for the rest of her life to determine whether her cancer is in remission or not.

Damages and Remedies

33. Plaintiff sues to recover all elements of compensable damages under Texas and/or Illinois law. Additionally, she seeks appropriate prejudgment interest thereon, as provided by law.

34. If the evidence at trial demonstrates the level of culpability necessary for an assessment of punitive or exemplary damages, then Plaintiff seeks an award in such amount as the Jury shall deem appropriate.

35. Plaintiff seeks attorneys' fees under her breach of contract theory of liability.

Jury Demand

36. Plaintiff invokes her constitutional right to trial by jury.

Prayer for Relief

WHEREFORE, Plaintiff prays that Defendant Abbott Laboratories be cited to appear and answer herein, and that upon the final trial of this case, a Final Judgment be entered by this Court in its favor against Defendant Abbott Laboratories as follows:

a. Awarding such compensatory and punitive damages to Plaintiff as are appropriate, plus interest and costs;

b. Awarding Plaintiff her attorneys fees and costs under her breach of contract theory; and

c. Awarding such other and further relief as is just and proper.

Respectfully submitted,

VICKERY, WALDNER & MALLIA, LLP

/s/ Arnold Anderson (Andy) Vickery

Arnold Anderson (Andy) Vickery
Texas Bar No. 20571800
Fred H. Shepherd
Texas Bar No. 24033056
One Riverway, Suite 1150
Houston, TX 77056-1920
Telephone: 713-526-1100
Facsimile: 713-523-5939
Email: andy@justiceseekers.com
Email: fred@justiceseekers.com

Certificate of Service

Once Abbott has answered, the CM/ECF system will effectuate service. However, a courtesy copy of this original Complaint has been provided to the following counsel for Defendant Abbott Laboratories:

John Donley, Esq.
Renee D Smith, Esq.
KIRKLAND & ELLIS, LLP
300 North LaSalle Street
Chicago IL 60654

/s/ Arnold Anderson (Andy) Vickery
Arnold Anderson (Andy) Vickery